## REMARKS

Claims 1-31 are listed as pending in the application, which claims have been rejected.

Reconsideration and withdrawal of the rejection of claims 1-31 are requested.

## DISCUSSION

### Change in Correspondence Address

Applicants respectfully direct the Examiner's attention to the executed, concurrently submitted Change of Correspondence Address Form and request acknowledgement of the receipt of same. The undersigned attorney was previously designated an Attorney of Record pursuant to the Associate Power of Attorney filed October 6, 2003 in the instant application. A copy of the Associate Power of Attorney is transmitted concurrently herewith for the Examiner's inspection.

### Objections

In the Office Action mailed July 28, 2005, the Examiner objected to Applicant's use of certain trademarks in the description and claims and the use of an embedded hyperlink.

Pursuant to the provisions of C.F.R. §1.125, Applicants submit herewith for the Examiner's consideration a substitute specification wherein the embedded hyperlink has been deleted and certain trademarks have, to the fullest extent possible, been generically defined. Added subject matter has been underlined and deleted matter has been indicated with strikethrough. An unmarked (clean) copy of the substitute specification has also been transmitted

concurrently herewith. The amendments made to the substitute specification, as reflected in the clean copy thereof, do not constitute the addition of new matter.

Acceptance of the substitute specification, and reconsideration and withdrawal of the objection to the specification are requested.

Rejection of claims 1-31 Under 35 U.S.C. §103

The Examiner further rejected claims 1-31 under 35 U.S.C. §103(a) as being unpatentable over Arneric, *et al.* (U.S. Pub. Appl'n. No. 2003/0060513 A1) and Hawley, *et al.* (U.S. Pub. Appl'n. No. 2003/0199582 A1) in view of Pediatric Pharmacotherapy (Vol. 2, (1996)) (Buck, *et al.*, hereinafter) and Gage, *et al.* (U.S. Pat. No. 5,922,914).

In response thereto, Applicants note that neither Arneric, *et al.*, nor Hawley, *et al.*, is a proper reference against the instant application.

Section 103(c) of 35 U.S.C. provides that "[s]ubject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

Statement of Common Ownership

Arneric, *et al.*, which claims priority to U.S. Serial No. 09/965,556, and the instant application, U.S. Serial No. 10/647,816, were, at the time the present invention was made, under an obligation of assignment to Pharmacia. In support thereof, Applicants refer to the Assignment recorded at Reel

012587, Frame 0825, a copy of which is transmitted concurrently herewith for the Examiner's consideration, and marked as "EXHIBIT A."

Hawley, *et al.*, which claims priority to U.S. Serial No. 10/127,875, and the instant application were, at the time the present invention was made, also under an obligation of assignment to Pharmacia. In support thereof, Applicants refer to the Assignments recorded at Reel 013286, Frame 0073, a copy of which is also transmitted concurrently herewith for the Examiner's consideration, and marked as "EXHIBIT B."

Support for the standing rejection must now derive solely from the teachings of the Gage *et al.*, and Buck, *et al.*, references. Nothing in Gage, *et al.*, or Buck, *et al.*, alone or in proper combination, renders the instant invention obvious.

Gage, *et al.*, teaches preparative processes for the synthesis of tolterodine hydrochloride and (R)-tolterodine (L)-tartrate. Buck, *et al.*, teaches, in a generic manner, components typically employed in pharmaceutical products, including sweetening agents, preservatives, colorants, and the like. Neither Gage, *et al.*, nor Buck, *et al.*, teach any pharmaceutical formulations comprising tolterodine, including the orally-deliverable, aqueous liquid formulations of the present invention that comprise water-soluble salts of tolterodine or tolterodine-related compounds. Further, neither Gage, *et al.*, nor Buck, *et al.*, teach the specific, effective dosage ranges of the tolterodine and tolterodine-related compounds of the present invention. Such dosage ranges are a non-obvious component of the invention, particularly in view of the poorly-acceptable astringent effect of aqueous solutions of tolterodine L-tartrate at concentrations of 1.0

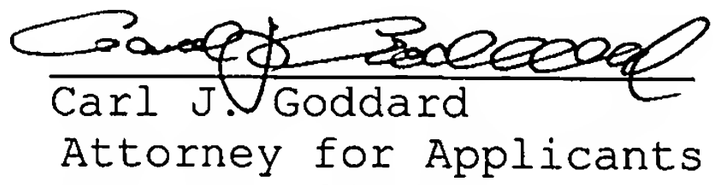
mg/ml or higher. The Examiner's attention is directed to, *inter alia*, pages 4-5, paragraph 0029, and pages 17-18, paragraph 0086, of the instant description. Still further, neither Gage, *et al.*, nor Buck, *et al.*, teach or disclose the acidic buffer system employed in the formulations of the present invention. Applicants note that aqueous solutions of tolterodine salts have been found to have optimum stability at a pH of between about 2 and 6, preferably about 4. However, at such lower pH ranges, anti-microbial agents, including sodium benzoate taught by Buck, *et al.*, have diminished efficacy. The Examiner's attention is directed to page 18, paragraph 0087, of the instant description. Accordingly, strict regulation of aqueous pH with concomitant regulation of the effective amounts of preservatives at low pH values, neither of which is taught by Gage, *et al.*, or Buck, *et al.*, are also non-obvious aspects of the present invention.

Reconsideration and withdrawal of the rejection of claims 1-31 are respectfully requested.

All claims are in condition for allowance. Such prompt and favorable action is respectfully solicited.

Respectfully submitted,

Date: October 28, 2005



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